April 8, 2004

Name of Petitioner: Coalition to Preserve DSHEA

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Subject of Petition: Erroneous Interpretation of the Statutory Definition of the Term "Dietary Supplement"

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1-23, 12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION

The Coalition to Preserve DSHEA (Coalition) submits this Petition to the Food and Drug Administration (FDA or agency) pursuant to 21 C.F.R. § 10.30 to request that the Commissioner of Food and Drugs reconsider recently articulated interpretations of section 201(ff) of the FD&C Act. Specifically, the Coalition asks that FDA reconsider statements made in recent agency documents: first, that the term "dietary substance" in section 201(ff)(1)(E) refers only to ingredients commonly used in human food or drink; and, second, that the statutory definition of dietary supplement excludes synthetic equivalents of specific constituents of botanical ingredients.

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The Coalition is comprised of major dietary supplement trade associations, including the American Herbal Products Association, the Council for Responsible Nutrition, and the National Nutritional Foods Association, as well as a number of leading companies engaged in the manufacturing, retail, and raw material supply segments of that industry.

I. ACTION REQUESTED

This Petition requests that FDA reconsider two recently articulated interpretations of section 201(ff) of the Federal Food, Drug, and Cosmetic Act addressing the definition of the term "dietary supplement."

II. STATEMENT OF GROUNDS

Prior to the enactment of the Dietary Supplement Health and Education Act of 1994[1] (DSHEA), the Federal Food, Drug, and Cosmetic Act (FD&C Act) included no dietary supplement category as such. Many in industry and in the general public believed that FDA was pursuing increasingly restrictive policies against the sale of such products. Congress and the courts expressed frustration with what they viewed as the agency's "*ad hoc*, patchwork regulatory policy on dietary supplements."[2] Senator Orrin Hatch (R-UT), DSHEA's principal sponsor in the Senate, summed up the impetus behind DSHEA this way: "Despite the

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[1] Pub. L. No. 103-417, 108 Stat. 4325 (1994).

[2] Pub. L. No. 103-417, § 2(15)(B).

voluminous scientific record indicating the potential health benefits of dietary supplements, the Food and Drug Administration has pursued a heavy-handed enforcement agenda against nutritional supplements which has forced the Congress to intervene on two previous occasions, and yet again with adoption of this amendment."[3] FDA's bias against dietary supplements was especially troubling to a Congress that had become increasingly cognizant that "the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies."[4]

A chief means by which Congress sought to restrain FDA from imposing marketing impediments was its establishment of a broad definition of "dietary supplement." That definition, which appears at section 201(ff)(1) of the FD&C Act, relies in part upon the following expansive list of ingredients that such products may contain:

> The term "dietary supplement" --
>
> (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

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[3] 140 Cong. Rec. S11710 (daily ed. August 13, 1994) (statement of Sen. Hatch). Among the congressional interventions to which Senator Hatch had referred was the enactment of legislation in 1976 that added a new Section 411 to the FD&C Act, relating to vitamins and minerals, and the enactment of a 14 month moratorium on FDA's implementation of a health claims statute because it believed the agency would do so in an overly-restrictive manner not in keeping with congressional intent. Dietary Supplement Act of 1992, Pub. L. No. 102-571, 106 Stat. 4500 (1992).

[4] Pub. L. No. 103-417, § 2(2).

(A) a vitamin;

(B) a mineral:

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).[5]

No provision of the statutory definition was more fundamental to fulfilling the Congressional objective of ensuring consumer access to a broad range of products than section 201(ff)(1)(E). Congress intended the clause to serve as a catchall for the large number of substances on the market that were not vitamins, minerals, botanicals, or amino acids.

This Petition addresses two recent FDA statements relating to the statutory definition of "dietary supplement" in 201(ff)(1). The first concerns the agency's statement that the term "dietary substance" in section 201(ff)(1)(E) refers only to dietary ingredients commonly used in

[5] Section 201(ff)(1) of the FD&C Act, 21 U.S.C. 321(ff)(1).

human food or drink.[6] The second involves the agency's statement that the enumerated dietary ingredient categories exclude synthetic equivalents of specific constituents of botanicals.[7]

The Coalition believes these statements conflict with both the clear meaning of the statute and Congress' intent to ensure consumer access to the broadest possible range of safe dietary supplement products. The Coalition also believes that these interpretations threaten new product introductions and subject to potential legal challenge significant existing industry products. Many small manufacturing and retail businesses, as well as larger established ingredient suppliers and manufacturers, would be adversely affected.

A. Use of Dietary Substances Not Commonly Used for Human Food or Drink

FDA has suggested that the term "dietary substance" in section 201(ff)(1)(E) should be understood to refer only to dietary ingredients commonly used in human food or drink.[8] This interpretation would substantially narrow the scope of the statutory definition of "dietary supplement." As noted above, however, Congress intended the definition to be construed broadly, a fact FDA has acknowledged in other proceedings.[9] Ironically, the specific provision FDA relies upon to impose its more circumscribed interpretation is the very one that

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[6] *E.g.*, Letter from Felicia B. Satchell, Director, Division of Standards and Labeling Regulations, CFSAN, FDA, to Jason S. Crush 2, Docket No. 1995S-0316 RPT 162 (August 29, 2002) (response to new dietary ingredient premarket notification for conjugated linoleic acid) .

[7] 69 Fed. Reg. 6788, 6793 (February 11, 2004).

[8] *See e.g.*, Letter from Felicia B. Satchell, Director, Division of Standards and Labeling Regulations, CFSAN, FDA, to Jason S. Crush, Docket No. 1995S-0316 RPT 162 (August 29, 2002).

Congress intended to serve as the chief vehicle by which to secure the intended broad construction.

Congress explicitly intended that section 201(ff)(1)(E) of the FD&C Act not be limited to substances commonly used for human food or drink. In fact, the Senate Committee report accompanying DSHEA reveals Congress' explicit expectation that numerous substances would fall within the statutory definition of "dietary supplement," even though they were not commonly used as human food or drink and were not vitamins, minerals, botanicals, or amino acids. Two such substances, Glucosamine Sulfate and Coenzyme Q 10, were highlighted in the report as examples of substances expected to be included among the dietary substances described at section 201(ff)(1)(E). Many other dietary substances that are not commonly used in food or drink were grandfathered under DSHEA because they were understood to fulfill the requirements of this subsection. These include such diverse ingredients as melatonin, shark cartilage, egg shell power, evening primrose oil, and royal jelly.

FDA derived its recent interpretation of the term "dietary substance," as it is used in section 201(ff)(1)(E), by relying upon a common dictionary definition. However, the agency neglected to note that the term "dietary" modifies not only section 201(ff)(1)(E), but the remainder of section 201(ff)(1) as well. If FDA's interpretation were correct, therefore, the only

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[9] 62 Fed. Reg. 49859, 49860 (September 23, 1997).

botanicals eligible for use in dietary supplements would be those commonly used for food.[10] Almost all botanical constituents would be removed from the market if FDA's interpretation were to stand.

FDA has previously stated that it "interprets the list of dietary ingredients that fall under the definition of 'dietary supplement' in section 201(ff) of the act as an explication of 'other similar nutritional substances' [in section 403(r)(5)(D)]."[11] Accordingly, the agency has relied upon a listing of substances enumerated in the context of Senate deliberations over the meaning of the latter statutory provision to better understand those substances included within the definition of "dietary supplement." In this regard, FDA recognized the following substances to be among the dietary ingredients encompassed by section 201(ff)(1):

> Primrose oil, black currant seed oil, coldpressed flax seed oil, "Barleygreen" and similar nutritional powdered drink mixes, Coenzyme Q 10, enzymes such as bromelain and quercetin, amino acids, pollens, propolis, royal jelly, garlic, orotates, calcium-EAP (colamine phosphate), glandulars, hydrogen peroxide

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[10] Note as well that FDA's circular reading of (E) is undermined by the fact that under section 201 (ff)(2)(B), a dietary supplement cannot be "represented as a conventional food or as a sole item of the diet." If a dietary ingredient cannot be a conventional food but must be "commonly used for food or drink," then it could only legally be a concentrate, metabolite constituent or extract of an ingredient commonly used for food. That renders section 201((ff)(1)(E) superfluous.

[11] Requirements for Nutrient Content Claims; Health Claims, and Statements of Nutritional Support for Dietary Supplements, 62 Fed. Reg. 49859, 49860 (September 23, 1997) (codified at 21 C.F.R. 101).

(H_2O_2), nutritional antioxidants such a [sic] superoxide dismutase (SOD), and herbal tinctures.[12]

As noted above, the synthetic form of some of these long–used dietary substances is commonly used in dietary supplements. Thus, FDA's recognition that these synthetic ingredients are encompassed by section 201(ff)(1)(E) implicitly affirms that the section includes synthetic substances that are not commonly used in human food or drink.[13]

B. Alternate Mechanisms for Ensuring the Safety of Dietary Supplements

The major concern before Congress when debating section 201(ff) was one of safety -- particularly a concern that the definition was so broad as to permit prescription drugs sold overseas to be marketed in the U.S. as dietary supplements. Testimony by FDA Commissioner Kessler pinpoints this definitional fight:

> Mr. Chairman, I don't have a problem if someone wants to sell those products as long as there is no problem with safety, and as long as they don't make a claim that can't be supported. If someone wants to put sawdust in a bottle and sell it for $14, it is okay with me as long as they don't put a claim that it is useful to prevent cancer, heart disease, diabetes, or arthritis. That is where I draw the line. When supplements are really being sold as drugs in disguise promoted to treat serious disease, then I believe we have a problem. Dietary Supplement Hearings before a Subcommittee of

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[12] *Id.*

[13] The Coalition will be submitting further examples of affected products in a subsequent addendum to this Petition.

the House Appropriations Committee, 103rd Congress, 1St Sess., pg. 82 (1993).

In debating the amended provision in August, 1994, shortly before passage, Senator Kennedy, the principal Senate opponent complained that:

> "... the Hatch legislation offers a definition of dietary supplement that many feel is too broad. It will allow certain products which are treated as prescription drugs in other countries or as unapproved drugs in this country, to be treated as a dietary supplements ..."[14]

Senator Hatch responded:

> "Drafters of the legislation were criticized for a definition of dietary supplement that some felt was overly broad. We have tried to tighten that up. ... Some then believed that the language would allow drugs such as taxol to be marketed as a dietary supplement. Senator Harkin and I worked some time after the markup to resolve that issue, and the language we present today addresses that concern."[15]

Senators Hatch and Harkin addressed the Taxol scenario in several ways in DSHEA. None undercut the broad definitional scope of section 201 (ff)(1) (E).

The *first* most critical safeguard is the new safety section. Section 402(f) added a new dietary ingredient adulteration clause, including a section providing emergency HHS powers for dangerous products. Point 1 of the DSHEA Statement of Agreement also preserves FDA's powers to prevent the import of foreign drugs.[16]

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[14] ___ Cong. Rec. S11705, 11708.

[15] Id. at S11709 .

[16] Congressional Record October 6, 1994 at H1180 (October 6, 1994)

The *second* safety screen is the 75-day new dietary ingredient pre-market notification. FDA has the ability to evaluate new substances under Section 413 and to enforce under 402(f)(1). [17]

> Section 413:
>
> There is a history of use or other evidence of safety establishing that the dietary ingredient ... will reasonably be expected to be safe.
>
> Section 402(f)(1):
>
> [a product is adulterated if it] "is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."

A *third* screen is the higher safety standard in the Section 402(f) adulteration standard for dietary supplements:

> [a product is adulterated if it is a] "dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use."

A *fourth* screen, partly related to safety, is Section 201(ff)(3) -- the race-to-the-market-provision -- which states that a product cannot be a dietary supplement if it was first marketed as a new drug or biologic[18] (or subject to a substantial, publicized IND). That

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[17] The new dietary ingredient section does not limit the form of dietary ingredients set forth in section 201(ff)(1)(E).

[18] Note that Congress included biologics as potential dietary ingredients (as well as synthetic drugs).

provision once again reflects Congress' awareness that non-foods could be dietary supplements – i.e., that non-food substances being examined for possible drug use might become dietary supplements if safe and otherwise compliant with Sections 201 and 413.

Section 201(ff)(1)(E) must thus be read *in para materia* with subsection (ff)(2) and with section 402(f)(1). As restrictive interpretation of section 201(ff)(1)(E) would adversely impact many dietary substances that have been used in dietary supplements since long before passage of DSHEA. That interpretation also effectively overrules Congress' expressed intent.

C. Use of Synthetic Equivalents to Specific Constituents of Dietary Ingredients

The following section addresses FDA's statement that synthetic equivalent versions of botanical ingredients do not constitute dietary ingredients under sections 201(ff)(1)(C) and (1)(F) of the FD&C Act.

Neither the legislative language nor the legislative history of DSHEA supports FDA's conclusion that section 201(ff) excludes synthetic equivalent versions of botanical constituents. Moreover, no provision of DSHEA expressly distinguishes between natural and synthetic sources of botanical constituents. In fact, with respect to dietary supplements, all references in the FD&C Act to synthetic versions of dietary ingredients equate such substances with their natural counterparts.[19]

1. Categories of dietary ingredients recognized to include synthetically derived versions

FDA's statement that synthetic versions of botanical constituents do not constitute dietary ingredients under section 201(ff) of the FD&C Act stands in sharp contrast to the undisputed

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[19] *See, e.g.*, section 411(a)(1)(C) (referring to the "combination or number of any synthetic or natural" vitamins, minerals, or other ingredients of food). Additionally, FDA has frequently observed that synthetic and natural versions of the same form of a nutrient or other dietary ingredient are chemically and functionally identical. *See* 62 Fed. Reg. 49826, 49841 (September 23, 1997) (finding no scientific evidence to suggest a meaningful difference between natural and synthetic forms of the same nutrient); 69 Fed. Reg. at 6807 (noting that the available evidence does not demonstrate that ephedrine from botanical sources is materially different from ephedrine from pharmaceuticals with respect to chemistry, potency, or physiological or pharmacological effects). Additionally, the variety of synthetic analogs of natural flavors that may be used in food products may be considered analogous. 21 C.F.R. 101.22.

inclusion of synthetic versions of other categories of dietary ingredients. Specifically, synthetic versions of vitamins described in section 201(ff)(1)(A), minerals described in section 201(ff)(1)(B), and dietary substances described in section 201(ff)(1)(E) are widely used in dietary supplements without controversy.

a. Synthetic versions of vitamins and minerals

Vitamins and minerals constitute two of the six categories of dietary ingredients enumerated in section 201(ff)(1), and both include synthetic versions of the ingredients. Reference in section 411(a)(1)(C) to "any synthetic or natural . . . vitamin, ... mineral, . . . or other ingredient of food" establishes that synthetic vitamins and synthetic minerals constitute ingredients of food. An FDA regulation deems a dietary supplement misbranded if its label or labeling represents or implies that a natural vitamin in a food is superior to an added or synthetic vitamin, thus demonstrating that synthetic as well as natural dietary ingredients are recognized as appropriate food ingredients. [20]

b. Synthetic equivalents to specific dietary substances for use to supplement the diet

Like vitamins and minerals that conform to sections 201(ff)(1)(A) and 201(ff)(1)(B) of the FD&C Act, respectively, dietary substances described in section 201(ff)(1)(E) may also be derived from synthetic sources. According to one FDA statement, however, these synthetic dietary substances are covered by section 201(ff)(1)(E) only if the synthetic substance *itself,*

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[20] 21 C.F.R. 101.9(k)(4).

rather than merely the natural dietary substance to which it is equivalent, is commonly used in human food or drink.[21]

This statement by FDA conflicts with the intent of Congress, as well as longstanding precedent. As noted above, section 201(ff)(1)(E) was drafted substantially to expand the scope of the dietary supplement definition to reach the large number of safe dietary substances on the market that were not vitamins, minerals, botanicals, or amino acids. FDA's statement threatens to undermine that Congressional objective. Although these statements are not in the form of regulations and thus do not constitute the formal position of the agency, the Coalition submits this Citizen Petition in order to obtain clarification of these matters.

The legislative history of DSHEA explicitly reveals that Congress intended that section 201(ff)(1)(E) include synthetic substances that are not themselves commonly used for human food or drink. When enacting DSHEA, Congress exempted dietary ingredients marketed in the United States before October 15, 1994 from premarket notification. [22] It did so after reviewing a large number of dietary substances that were currently on the market. In the course of its review, Congress considered synthetic sources of dietary substances that were not vitamins, minerals, amino acids, or botanicals, and that also were not commonly used for human food or drink.[23] Notably, Congress cited scientific evidence demonstrating the value of two such substances,

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[21] Letter from Susan J. Walker, Acting Director, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, CFSAN, FDA, to I. Scott Bass & Diane C. McEnroe 2 (March 12, 2003).

[22] Section 413 of the FD&C Act, 21 U.S.C. 350b.

[23] Sen. Rep. 103-410, at 8-9 (1994).

Glucosamine Sulfate and Coenzyme Q 10,[24] as illustrative of the importance of this broad group of ingredients that it intended to cover under section 201(ff)(1)(E).[25]

Section 413(a)(2) of the FD&C Act requires companies to submit premarket notification with respect to new dietary ingredients. That section explicitly encompasses "chemically altered" ingredients as possible dietary ingredients.

Some FDA rulings with regard to such notifications have accepted the appropriateness of natural or synthetic dietary ingredients that are not themselves commonly used in human food or drink. For example, the agency has voiced no objection to premarket filings with respect to plant stanols/sterols. Despite their identification as plant materials, these products are forms of tall oil, which are derived as by-products of the kraft paper pulping process. Thus, such substances are waste products, and are not commonly used for human food or drink.[26] Moreover, these phytosterols are not vitamins, minerals, botanicals, amino acids, nor do they constitute a concentrate, metabolite, constituent, extract, or combination of any other dietary ingredient. FDA's lack of objection to the premarket notification filed with respect to phytosterols is also consistent with a broad interpretation of the scope of section 201(ff)(1)(E).[27]

2. Extending recognition of synthetic vitamins, minerals, and dietary substances to other categories of dietary ingredients

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[24] Although Coenzyme Q 10 exists in both natural and synthetic form, it is the synthetic version that predominantly is used in dietary supplements.

[25] Sen. Rep. 103-410, at 8-9 (1994).

[26] Docket No. OOP-1275; Docket No. OOP-1276.

As noted above, section 201(ff)(1) includes six categories of dietary ingredients. FDA does not contest that synthetic versions of vitamins and minerals are included among the ingredients described at sections 201(ff)(1)(A) and 201(ff)(1)(B), respectively. Nor does the agency deny that synthetic dietary substances may be included among ingredients described at section 201(ff)(1)(E), if the substance is commonly used in human food or drink. Moreover, as the above discussion demonstrates, FDA's interpretation of section 201(ff)(1)(E) contradicts Congress' express intent, and is inconsistent with the nature of both the dietary substances marketed as dietary supplements since before October 15, 1994, as well as several new dietary ingredients to which the agency has expressed no opposition.

Importantly, each of the six categories of ingredients enumerated in section 201(ff)(1) bears an identical status with respect to the statutory process of defining a "dietary supplement." Neither section 201(ff) nor any other provision of the FD&C Act qualifies, distinguishes, or imposes differential requirements with respect to any of the six categories of ingredients. Thus, for example, for purposes of defining a dietary supplement, vitamins are treated no differently than minerals or botanicals. As evidence of its recognition of this fact, FDA has stated: "The Act does not support treating supplements of vitamins and minerals any differently than any other type of supplements."[28]

Nowhere in the statutory definition of "dietary supplement," or in any other provision of the FD&C Act dealing with dietary ingredients, is there any indication that Congress intended to

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[27] FDA has also not objected to a premarket notification filed for Humifulvate, a by-product of Hungarian peat. Docket No. 95S-0316.

restrict an ingredient category based on its natural or synthetic derivation. Moreover, the Coalition is aware of no reasonable policy basis to justify allowing dietary supplements to contain a synthetic substance commonly used in food, while disallowing a synthetic substance that is identical to a natural ingredient commonly used in food. Accordingly, it is most reasonable to conclude that Congress intended to allow synthetic versions of, not only vitamins, minerals, and dietary substances commonly used in human food or drink, and also each of the remaining categories of dietary ingredients enumerated in section 201(ff)(1) of the FD&C Act.

3. Synthetic equivalents in Section 201(ff)(1)(F)

Section 201(ff)(1)(F) of the FD&C Act provides that a dietary supplement ingredient includes a concentrate, metabolite, constituent, extract, or combination of any ingredient described in sections 201(ff)(1)(A) through 201(ff)(1)(E). The FD&C Act does not define these terms. One FDA employee has made the statement that "a substance that has never been physically a part of the whole cannot be a constituent or an extract of that whole."[29] FDA recently made a similar statement, without explanation or analysis, in its final rule declaring

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[28] 62 Fed. Reg. 49826, 48841 (September 23, 1997).

[29] Letter from Susan J. Walker, Acting Director, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, CFSAN, FDA, to I. Scott Bass & Diane C. McEnroe 2 (March 12, 2003).

dietary supplements containing ephedrine alkaloids adulterated.[30] If this were to be accepted, a synthetic equivalent of a constituent of a botanical cannot be considered a dietary supplement under section 201(ff)(1) because it will never have been physically a part of the botanical itself.

No distinction is made among the ingredient components enumerated at section 201(ff)(1)(F) with respect to the statutory definition of a dietary supplement. The terms "concentrate," "metabolite," "constituent," and "extract" are used in an identical manner, and none is subject to special statutory qualifications, distinctions, or conditions. Accordingly, there exists no statutory basis upon which to conclude that concentrates, metabolites, constituents, or extracts are uniquely restricted with respect to whether they may derived from a nature-identical synthetic source.

Metabolites used as ingredients in dietary supplements are necessarily synthetic. They do not occur in nature. Since the FD&C Act limits use of metabolites in dietary supplements no less than it does use of any other component enumerated in section 201(ff)(1)(F), Congress could not reasonably have intended to exclude synthetic constituents of dietary ingredients. And since, as discussed above, each category of dietary ingredient enumerated in section 201(ff)(1) bears an identical status with respect to its role in defining a dietary supplement, synthetic equivalents of constituents of dietary substances intended to supplement the diet constitute potential dietary ingredients under DSHEA. Therefore, a synthetic equivalent of a constituent of a botanical also must be recognized as a permissible dietary ingredient.

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[30] 69 Fed. Reg. at 6793 (asserting that synthetic sources of constituents or extracts of botanicals cannot be dietary ingredients under section 201(ff)(1) because they are not themselves (continued...)

D. Conclusion

For the reasons stated above, the Coalition respectfully requests that FDA reconsider untenable interpretations that would narrow the scope of section 201(ff) of the FD&C Act.

III. CLAIM FOR CATEGORICAL EXCLUSION

The Coalition expects the action requested in this Petition to have no significant effect on the quality of the human environment. The requested action is among those subject to categorical exclusion provided under one or more subsections of 21 C.F.R. 25.30. Petitioner has no knowledge of extraordinary circumstances related to its request.

CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the Petition.

Coalition to Preserve DSHEA

David Seckman

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constituents or extracts of the botanical).

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April 8, 2004

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Re: Citizen Petition:
"Erroneous Interpretation of the Statutory Definition of the Term Dietary Supplement"

Dear Sir or Madam:

Enclosed please find three copies of the above-captioned document for filing.

Very truly yours,

I. Scott Bass

Enclosure

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